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Petition  
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PATENT

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Date of Deposit January 9, 2002

TTC Docket No. 017516-007400US

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BOX PATENT EXTENSION  
Commissioner for Patents  
Washington, D.C. 20231

By: [Signature]  
Daniel Miranda

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re patent of:

Phillip S. Green

Patent No.: 5,808,665

Issued: September 15, 1998

Title: ENDOSCOPIC SURGICAL INSTRUMENT  
AND METHOD FOR USE

**REQUEST FOR RECONSIDERATION  
FOR PATENT TERM EXTENSION UNDER 35 U.S.C. § 156**

Hon. Commissioner of Patents and Trademarks  
Box: Patent Extension  
Washington, D.C. 20231

**RECEIVED**

JAN 25 2002

Sir:

OFFICE OF PETITIONS  
DEPUTY A/C PATENTS

Applicants respectfully request reconsideration for a patent term extension of U.S. Patent No. 5,808,665. A patent term extension request was filed under 35 U.S.C. § 156 on September 11, 2000 in light of Food and Drug Administration (hereinafter "FDA") approval of the da Vinci<sup>TM</sup> Robotic Surgery System. A Final Determination of Ineligibility (hereinafter "Determination") was mailed from the Patent Office on November 14, 2001.

Dismissal of the application for the subject patent term extension was apparently based on the determination by the Commissioner of Patents and Trademarks (hereinafter "Commissioner") that the da Vinci<sup>TM</sup> System underwent regulatory review under Section 510(k) of the Federal Food, Drug, and Cosmetic Act (hereinafter "FFDCA"). Determination, page 2. However, as properly determined by the FDA, the da Vinci<sup>TM</sup> system was subjected to a regulatory review period as defined by 35 U.S.C. §156(a)(4), including regulatory review under section 515 of the FFDCA. FDA letter dated October 2, 2001.

The regulatory review of the da Vinci™ System was conducted under both sections 515 and 510(k) of Chapter 5 of the FFDCA, with approval eventually being granted under 510(k). As the da Vinci™ System was subjected to regulatory review under section 515, Applicants are entitled to a patent term extension. Per 35 U.S.C. § 156(d)(2), the Secretary of Health and Human Services is responsible for determining the Regulatory Review Period for medical devices, and this matter was properly referred to the FDA. In a preliminary eligibility decision, the FDA informed the Commissioner that a “review of the Food and Drug Administration’s official records indicates that this product **was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4).**” *Id* (Emphasis added).

Reviewing the language of the statute, 35 U.S.C. § 156(a)(4), requires that, “the product has been subject to a regulatory review period before its commercial marketing or use.” For medical devices, the term “regulatory review period” is defined in § 156(g)(3)(B) as follows:

- (i) the period beginning on the date a clinical investigation on human involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515, and
- (ii) the period beginning on the date an application was initially submitted with respect to the device under section 515 and **ending on the date such application was approved under such Act** or the period beginning on the date a notice of completion of a product development protocol was initially submitted under section 515(f)(5) and ending on the date the protocol was declared completed under section 515(f)(6).

(Emphasis added). Therefore, within the plain language of 35 U.S.C. § 156(a)(4) and § 156(g)(3)(B), a regulatory review period begins at the initiation of human clinical trials and ends on approval under the “Act,” i.e. the FFDCA, which includes both sections 515 and 510(k) of Chapter 5.

The FDA correctly verified that Applicants meet the statutory requirements for a regulatory review period under the plain language of 35 U.S.C. § 156(a)(4) and § 156(g)(3)(B). *Id*. Specifically, Applicants began their first clinical investigations on humans on July 27, 1998. On January 17, 1999 Applicants submitted a section 510(k) application

#K990144 to the FDA seeking laparoscopic approval for its da Vinci™ System. On May 19, 1999, the FDA reclassified the da Vinci™ System into a class III device requiring Pre-Market Approval (hereinafter "PMA") under section 515. Applicants complied with the FDA mandated reclassification by (a) submitting a complete PMA application #P990079 on November 18, 1999 based on the same clinical data gathered during its earlier human clinical investigations, and (b) requesting that the FDA approve the da Vinci™ System under section 515 for laparoscopic procedures. The FDA accepted the PMA application for filing on November 29, 1999. On May 22, 2000, the FDA again reclassified the da Vinci™ System so that its corresponding PMA application #P990079, which had been reviewed for over a year under section 515, was reverted back to a 510(k). On July 11, 2000, the FDA approved the 510(k) application #K990144, with the submission date marked as November 18, 1999, the date the PMA application #P990079 under section 515 was submitted to the FDA.

As a final matter, Applicants gratefully acknowledge the Patent Office's correct determination that the Patent Term Extension request was timely filed. Determination, page 1. The FDA communication raised the issue as to whether the application was timely filed within the sixty-day (60) statutory period under 35 U.S.C. § 156(d)(1). FDA letter dated October 2, 2001. While the FDA often possesses information which is not readily available to the Commissioner, the Commissioner has primary responsibility for the eligibility determination. See M.P.E.P. § 2756. The Commissioner correctly determined that the present application was timely filed within the sixty-day (60) period permitted for submission of such applications for extension of patent terms. Determination, page 1. The date of product approval was July 11, 2000. The present patent term extension application was filed on Monday, September 11, 2000. Sixty days after the approval date of the product was Saturday, September 9, 2000. 35 U.S.C. § 21(b) states that

When the day, or the last day, for taking any action or paying any fee in the United States Patent and Trademark Office falls on Saturday, Sunday, or a federal holiday within the District of Columbia, the action may be taken, or the fee paid, on the next succeeding secular or business day.

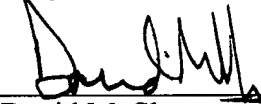
As Monday, September 11, 2000 was the next succeeding business day following the last day (Saturday, September 9, 2000), the application was timely filed.

As the FDA has verified that the present application satisfies the statutory

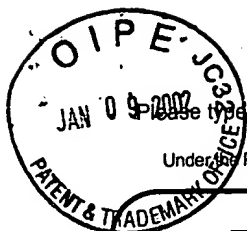
Phillip S. Green  
Patent No.: 5,808,665  
Page 4

requirements for a regulatory review period under 35 U.S.C. § 156(a)(4) and the Commissioner has determined that the present application was timely filed within the sixty-day (60) period permitted for submission of such applications for extension of patent terms, the last day of said sixty-day (60) period being September 11, 2000, the present application qualifies for a patent term extension. For the foregoing reasons, reconsideration and granting of Applicants application for patent term extension is respectfully requested.

Respectfully submitted,

  
\_\_\_\_\_  
David M. Shaw  
Reg. No. 38,688  
Chief Patent Counsel  
Intuitive Surgical, Inc.  
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PTO/SB/21 (08-00)

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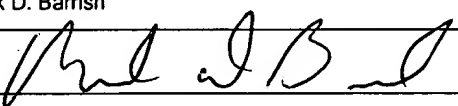
<b>TRANSMITTAL FORM</b> <i>(to be used for all correspondence after initial filing)</i>	<b>Application Number</b>	08/709,965	
	<b>Filing Date</b>	September 9, 1996	
	<b>First Named Inventor</b>	GREEN, Phillip S.	
	<b>Group Art Unit</b>		
	<b>Examiner Name</b>		
<b>Total Number of Pages in This Submission</b>	7	<b>Attorney Docket Number</b>	017516-007400US

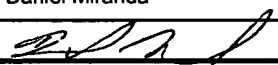
ENCLOSURES (check all that apply)		
<input checked="" type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Assignment Papers (for an Application)	<input type="checkbox"/> After Allowance Communication to Group
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment / Response	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition Routing Slip (PTO/SB/69) and Accompanying Petition	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Status Letter
<input checked="" type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Terminal Disclaimer	Request for Reconsideration for Patent Term Extension under 35 U.S.C §156 and Return Postcard
<input type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> Request for Refund	
<input type="checkbox"/> Certified Copy of Priority Document(s)	<input type="checkbox"/> CD, Number of CD(s)	
<input type="checkbox"/> Response to Missing Parts/ Incomplete Application	Remarks	The Commissioner is authorized to charge any additional fees to Deposit Account 20-1430.
<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53		

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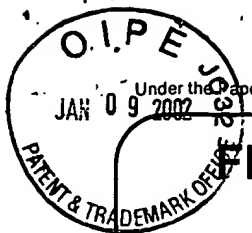
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DEPUTY A/C PATENTS

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT		
<b>Firm and Individual name</b>	Townsend and Townsend and Crew LLP Mark D. Barrish	
<b>Signature</b>	 Reg. No. 36,443	
<b>Date</b>	January 9, 2002	

CERTIFICATE OF MAILING		
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<b>Typed or printed name</b>	Daniel Miranda	
<b>Signature</b>		<b>Date</b> January 9, 2002

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Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

FEE TRANSMITTAL for FY 2001		Complete if Known	
		Application Number	08/709,965
Patent fees are subject to annual revision.		Filing Date	September 9, 1996
		First Named Inventor	GREEN, Philip S.
		Examiner Name	
		Group Art Unit	
TOTAL AMOUNT OF PAYMENT (\$)		55	Attorney Docket No. 017516-007400US

METHOD OF PAYMENT		FEE CALCULATION (continued)																																																																																																																																																																																																							
<p>1. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge indicated fees and credit any over payments to:</p> <p>Deposit Account Number: 20-1430</p> <p>Deposit Account Name: Townsend and Townsend and Crew LLP</p> <p><input checked="" type="checkbox"/> Charge Any Additional Fee Required Under 37 CFR 1.16 and 1.17</p> <p><input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27</p>		<p>3. ADDITIONAL FEES</p> <table border="1"><thead><tr><th>Large Fee Code</th><th>Entity Fee (\$)</th><th>Small Fee Code</th><th>Entity Fee (\$)</th><th>Fee Description</th><th>Fee Paid</th></tr></thead><tbody><tr><td>105</td><td>130</td><td>205</td><td>65</td><td>Surcharge - late filing fee or oath</td><td></td></tr><tr><td>127</td><td>50</td><td>227</td><td>25</td><td>Surcharge - late provisional filing fee or cover sheet.</td><td></td></tr><tr><td>139</td><td>130</td><td>139</td><td>130</td><td>Non-English specification</td><td></td></tr><tr><td>147</td><td>2,520</td><td>147</td><td>2,520</td><td>For filing a request for reexamination</td><td></td></tr><tr><td>112</td><td>920*</td><td>112</td><td>920*</td><td>Requesting publication of SIR prior to Examiner action</td><td></td></tr><tr><td>113</td><td>1,840*</td><td>113</td><td>1,840*</td><td>Requesting publication of SIR after Examiner action</td><td></td></tr><tr><td>115</td><td>110</td><td>215</td><td>55</td><td>Extension for reply within first month</td><td>55</td></tr><tr><td>116</td><td>400</td><td>216</td><td>200</td><td>Extension for reply within second month</td><td></td></tr><tr><td>117</td><td>920</td><td>217</td><td>460</td><td>Extension for reply within third month</td><td></td></tr><tr><td>118</td><td>1,440</td><td>218</td><td>720</td><td>Extension for reply within fourth month</td><td></td></tr><tr><td>128</td><td>1,960</td><td>228</td><td>980</td><td>Extension for reply within fifth month</td><td></td></tr><tr><td>119</td><td>320</td><td>219</td><td>160</td><td>Notice of Appeal</td><td></td></tr><tr><td>120</td><td>320</td><td>220</td><td>160</td><td>Filing a brief in support of an appeal</td><td></td></tr><tr><td>121</td><td>280</td><td>221</td><td>140</td><td>Request for oral hearing</td><td></td></tr><tr><td>138</td><td>1,510</td><td>138</td><td>1,510</td><td>Petition to institute a public use proceeding</td><td></td></tr><tr><td>140</td><td>110</td><td>240</td><td>55</td><td>Petition to revive - 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late filing fee or oath		127	50	227	25	Surcharge - late provisional filing fee or cover sheet.		139	130	139	130	Non-English specification		147	2,520	147	2,520	For filing a request for reexamination		112	920*	112	920*	Requesting publication of SIR prior to Examiner action		113	1,840*	113	1,840*	Requesting publication of SIR after Examiner action		115	110	215	55	Extension for reply within first month	55	116	400	216	200	Extension for reply within second month		117	920	217	460	Extension for reply within third month		118	1,440	218	720	Extension for reply within fourth month		128	1,960	228	980	Extension for reply within fifth month		119	320	219	160	Notice of Appeal		120	320	220	160	Filing a brief in support of an appeal		121	280	221	140	Request for oral hearing		138	1,510	138	1,510	Petition to institute a public use proceeding		140	110	240	55	Petition to revive - unavoidable		141	1,280	241	640	Petition to revive - unintentional		142	1,280	242	640	Utility issue fee (or reissue)		143	460	243	230	Design issue fee		144	620	244	310	Reissue issue fee		122	130	122	130	Petitions to the Commissioner		123	50	123	50	Petitions related to provisional applications.		126	180	126	180	Submission of Information Disclosure		581	40	581	40	Recording each patent assignment (prepaid Uniform Patent Properties)		146	740	246	370	Filing a submission after final rejection (37 CFR § 1.129(a))		149	740	249	370	For each additional invention to be examined (37 CFR § 1.129(b))		179	740	279	370	Request for Continued Examination (RCE)		169	900	169	900	Request for expedited examination of a design application		Other fee (specify)						The Commissioner is authorized to charge any additional fees to the above noted Deposit Account.						*Reduced by Basic Filing Fee Paid						SUBTOTAL (3)					(\$)55
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\*\*or number previously paid, if greater; For Reissues, see above

SUBMITTED BY		Complete (if applicable)			
Name (Print/Type)	Mark D. Barrish	Registration No. (Attorney/Agent)	36,443	Telephone	650-326-2400
Signature				Date	January 9, 2002

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